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(54) Title: DRY POWER INHALER DEVICES AND DRY POWER FORMULATIONS FOR ENHANCING DOSING EFFICIENCY

(57) Abstract: The present invention relates to enhancing the dosing efficiency of pharmaceutical dry powder formulations administered by pulmonary inhalation. In particular, the present invention relates to the provision of dry powder inhalers and dry powder compositions which reproducibly achieve a much higher delivered dose of the pharmaceutically active agent than currently achieved.

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# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB2004/001628

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/16 A61K47/18 A61K9/14

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, EMBASE, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/067902 A (ADVANCED INHALATION RES INC ; BASU SUJIT K (US); DEEVER DANIEL R (US);) 6 September 2002 (2002-09-06)	4-6, 8, 12-14, 34-40
Y	page 23, lines 13-17 page 2, line 17 - page 3, line 14 page 16, line 30 - page 17, line 6 page 22, lines 19-22 examples 1A, 2-6 ----- -/--	7

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

\*Z\* document member of the same patent family

Date of the actual completion of the international search

11 February 2005

Date of mailing of the international search report

25.02.2005

Name and mailing address of the ISA

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# INTERNATIONAL SEARCH REPORT

International Application No  
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/13893 A (ADVANCED INHALATION RES INC ; BATYCKY RICHARD P (US); NIVEN RALPH W (U) 1 March 2001 (2001-03-01)	4-6,8, 12-14, 34-40
Y	page 18, lines 12-15 page 5, lines 1-6 page 5, line 21 - page 6, line 8 page 9, line 27 - page 10, line 3 page 18, line 22 - page 19, line 3 page 20, lines 11-25 examples 1-4	7
X	US 2002/071871 A1 (SNYDER HERM ET AL) 13 June 2002 (2002-06-13)	4-8, 12-14, 34-40
Y	paragraph '0019! paragraphs '0067!, '0069! paragraph '0075!; example 3	7
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	paragraphs '0012! - '0014! paragraph '0034! paragraphs '0041! - '0043! paragraph '0049!	
X	US 2003/055034 A1 (MONTGOMERY ALAN BRUCE) 20 March 2003 (2003-03-20) paragraphs '0244!, '0247! paragraph '0253! claims 25-27	9-14, 33-40
X	US 6 045 828 A (BYSTROEM ET AL) 4 April 2000 (2000-04-04)	9,10, 12-14, 33-40
	example 1	
X	WO 91/16038 A (TORAY INDUSTRIES, INC; PLATZ, ROBERT, M) 31 October 1991 (1991-10-31) examples 1,2	9,12-14, 33-40
A	WO 01/78693 A (CHIESI FARMACEUTICI S.P.A; STANIFORTH, JOHN, NICHOLAS; VODDEN MORTON,) 25 October 2001 (2001-10-25) page 15, lines 5-10 claims 10,11; example 1	9-14, 33-40

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB2004/001628

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1-3, 15-32  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB2004 /001628

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1(part)-3(part),4-8,12(part)-32(part),34(part)-40(part)

Dry powder inhaler device characterized in that it comprises a dry powder formulation produced by a defined spray drying process

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2. claims:

1(part)-3(part),9-11,12(part)-32(part),  
33,34(part)-40(part)

Dry powder inhaler device characterized in that it comprises a dry powder formulation produced by a defined micronisation process (jet milling)

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## INTERNATIONAL SEARCH REPORT

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1-3,15-32

The present claims 1-3 and 15-32 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined.

The claims attempt to define the subject-matter in terms of a result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Moreover, the claimed functional statements do not enable the skilled person to determine which technical features are necessary to perform the stated functions.

Accordingly, no meaningful search is possible for claims 1-3 and 15-32.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# INTERNATIONAL SEARCH REPORT

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International Application No  
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